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Pesticide Fact Sheet Number 176: Ethephon

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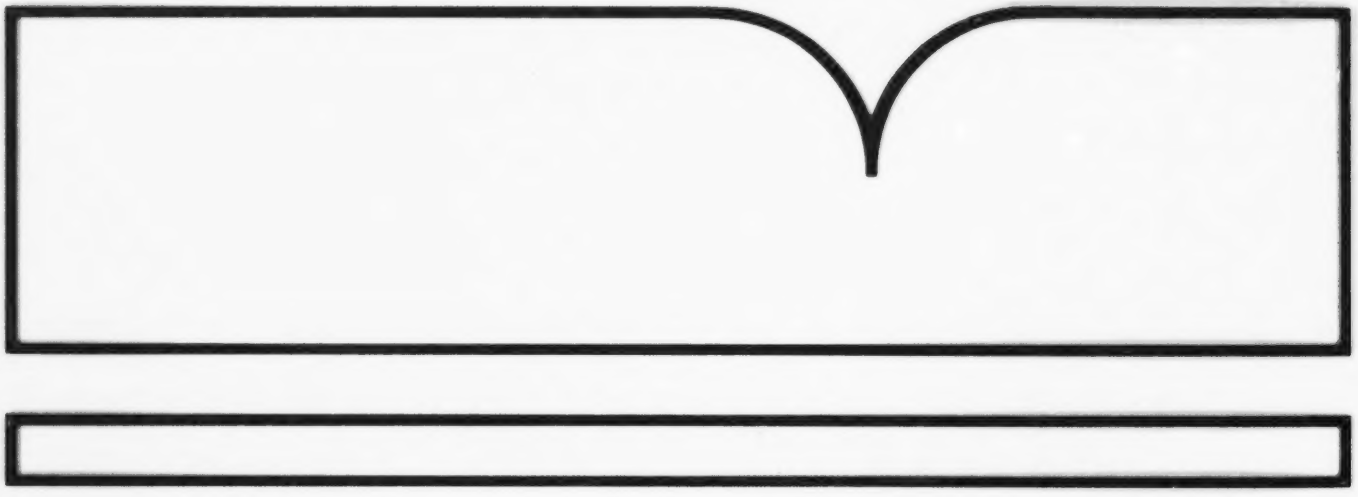

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16. Abstract (Limit: 200 words)

This document contains up-to-date chemical information, including a summary of the Agency's regulatory position and rationale, on a specific pesticide or group of pesticides. A Fact Sheet is issued after one of the the following actions has occurred.

1. Issuance or reissuance of a registration standard,
2. Issuance of each special review document,
3. Registration of a significantly changed use pattern,
4. Registration of a new chemical, or
5. An immediate need for information to resolve controversial issues relating to a specific chemical or use pattern.

17. Document Analysis a. Descriptors

Pesticides, regulations, Chemical Information Fact Sheet, Use Patterns, science findings.

b. Identifiers/Open-Ended Terms

c. COSATI Field/Group

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EPA

Pesticide Fact Sheet

Name of Chemical: Ethephon
Reason for Issuance: Registration Standard
Date Issued: September 29, 1988
Fact Sheet Number: 176

1. Description of Chemical

Generic Name: Ethephon
Common Name: Ethephon
Trade Names: Brometlor, Cerone, Chlorethephon (New Zealand), Ethrel, Florel, Prep and Flordimex
EPA Shaughnessy Code: 099801
Chemical Abstracts Service (CAS) Number: 16672-87-0
Year of Initial Registration: 1973
Pesticide Type: Growth Regulator
U.S. and Foreign Producers: AmChem/Union Carbide
Rhone-Poulenc

2. Use Patterns and Formulations

Application Sites: To enhance fruit ripening, flower initiation, fruit and leaf abscission, and breaking of apical dominance in apples, barley, wheat, blackberries, boysenberry, blueberry, cantaloupe, cherry (tart and sweet), cotton, cucumber, squash and pumpkin (hybrid seed production), figs, cucumber (pickling), filberts, grapes, lemon, tangerine, tangelo, pepper, pimento, tomato, walnut, tobacco (flue cured), ornamentals, guava, grapes for table and raisin production, pineapples, sugarcane, coffee beans, cottonseed, macadamia nuts, trees (forest and shelterbelt) and cranberries.

Mechanism of Action: Generation of ethylene after application (ethylene is a naturally-produced plant hormone).

Types of Formulations: Emulsifiable concentrate, soluble concentrates/liquids, ready-to-use liquids.

Types and Methods of Application: Broadcast by ground or aerial equipment.

Application Rates: Vary from 0.08 to 2.0 pounds of active ingredient per acre depending upon the use site and desired effects.

3. Science Findings

Chemical Characteristics:

Empirical Formula: $C_2H_6ClO_3P$
Molecular Weight: 144.5
Physical State: Waxy, solid
Color: White
Melting Point: 74 to 75 °C
Solubility: Very soluble in water, alcohol, propylene glycol; very slightly soluble in aromatic solvents.

Toxicology Characteristics:

Acute Effects

Acute Oral Toxicity: 1.6 g/kg rats (Toxicity Category III)

Acute Dermal Toxicity: > 5 g/kg rabbits (Toxicity Category III)

Acute Inhalation: Not available

Primary Eye Irritation: Not available, but assumed to be corrosive based on the primary dermal results

Primary Skin Irritation: Score 6.75 (Corrosive) rabbits (Toxicity Category I)

Delayed Neurotoxicity Hen: No signs of neurotoxicity

Sub-Chronic Effects

No adequate data are available on subchronic oral toxicity in rats or dogs. However, the requirement for subchronic studies in the rodent and non-rodent will be waived if the required chronic studies are acceptable.

Chronic Effects

Sprague-Dawley Rats - 18 Months: NOEL for cholinesterase activity is 15 mg/kg/day (supplementary data).

Beagle Dogs - 2-Year: NOEL for source A* ethephon was 7.5 mg/kg/day (supplementary data).

Swiss Albino Mouse - 18-Month oncogenicity study: NOEL for RBC cholinesterase activity is < 4.5mg/kg/day which was the lowest dose tested (LDT) (supplementary data).

Oncogenicity

The available data are not adequate to assess the oncogenic potential of ethephon. In the rat and mouse studies submitted, only chronic effects were observed and these effects are discussed under the chronic toxicity section.

Teratology

Rat: NOEL for maternal and embryo/fetal toxicity is 600 mg/kg/day. NOEL for teratogenic effects is 600 mg/kg/day.

Rabbit: NOEL is 50 mg/kg/day based on fetal resorptions at higher dose levels tested.

Reproduction: No adequate data available.

Mutagenicity: Salmonella typhimurium indicate no mutagenic effect up to 1000 ug/100 uL without activation. No acceptable data are available for chromosomal aberrations, primary DNA damage, or other genotoxic effects.

Metabolism: A rat metabolism study is required.

Possible Presence of Contaminant of Toxicological Concern

The Agency finds that residues of monochloroacetic acid may be found in ethephon-treated commodities. Monochloroacetic acid is a potential degradation product of an impurity in ethephon, monochloroethyl ester of (2-chloroethyl)-phosphonic acid. Monochloroacetic acid is an extremely toxic metabolic inhibitor and has been prohibited from addition to food under 21 CFR 189.155. Analysis of certain food and feed crops for residues of this contaminant are required.

Major Routes of Exposure

Dermal, Inhalation

Physiological and Biochemical Behavioral Characteristics:

Metabolism: Acceptable metabolism data are available for plants and ruminants. The residue of concern in plant commodities, ruminant tissues and milk is ethephon per se. Additional data are required regarding metabolism in poultry tissues and eggs.

* In the study there were two, apparently different, sources of the chemical tested and reported as source A and source B.

Possible Presence of Impurities: Available data indicate that technical ethephon products may contain 2-chloroethanol as an impurity. 2-Chloroethanol is extremely toxic via the inhalation route and has caused human deaths. Because of its volatility, 2-choroethanol is unlikely to be present in ethephon end use products in amounts high enough to pose an inhalation hazard. However, the impurity could pose a hazard when technical or manufacuring use products are stored or used in poorly ventilated spaces. Under these conditions, 2-chloroethanol vapors could accumulate to levels which may be hazardous to workers in the area. The Agency is requiring submission of product chemistry data to assess the extent of hazard posed by 2-choroethanol.

Environmental Characteristics:

Preliminary Adsorption and Leaching Characteristics: Data are required on leaching, volatility, and hydrolysis of ethephon to characterize the potential to reach ground water.

Ecological Characteristics:

Data are sufficient to characterize ethephon as slightly toxic to birds (Lc50 804 mg/kg quail, 3750 ppm ducks). Laboratory and field studies indicate that ethephon is slightly toxic to fish (Lc50 180 mg/L bluegill, 170 mg/L trout (average)).

Tolerance Assessment:

List of crops and Tolerances: (CFR 40 180.300)

Commodity	Tolerance (ppm)
Apples	5
Barley, grain	2.0
Barley, straw	10.0
Blackberries	30
Blueberries	20
Cantaloupes	2
Cattle, meat byproducts (mbyp)	0.1
Cattle meat	0.1
Cattle fat	0.1
Cherries	10
Coffee beans	0.1 (N)
Cottonseed	2.0
Cranberries	5
Cucumbers	0.1
Figs	5
Filberts	0.5
Goats, fat	0.1
Goats, mbyp	0.1
Goats, meat	0.1

Commodity	Tolerance (ppm)
Grapes	2.0
Hogs, fat	0.1
Hogs, mbyp	0.1
Hogs, meat	0.1
Horses, fat	0.1
Horses, mbyp	0.1
Horses, meat	0.1
Lemons	2
Macadamia nuts	0.5
Milk	0.1
Peppers	30
Pineapples	2
Pineapple fodder	3
Pineapple forage	3
Pumpkins	0.1
Sheep, fat	0.1
Sheep, mbyp	0.1
Sheep, meat	0.1
Tangerines	0.5
Tangerine hybrids	0.5
Tomatoes	2
Walnuts	0.5
Wheat, grain	2.0
Wheat, straw	10.0
Guavas	0.1
Sugarcane Hawaii only	0.1

40 CFR 185.2700 and 186.2700 (food and feed additive)

Barley milling fractions except flour	5.0
Wheat milling fractions except flour	5.0
Raisins	12.0
Raisin waste	65.0
Sugarcane molasses	1.5
Barley milling fractions except flour	5.0
Wheat milling fractions except flour	5.0

Results of Tolerance Assessment: The PADI for ethephon has recently been revised by the Agency ADI Committee and is now established at 0.005 mg/kg/day (0.5 mg/kg/day for a LEL, and an uncertainty factor of 100). This value is based on an LEL of 0.5 mg/kg/day for a decrease in plasma cholinesterase activity in a 16-day study in humans. An uncertainty factor of 100 is derived from a factor of 10 for the variation in the susceptibility of humans, and a factor of 10 for the use of an LEL instead of a NOEL. The PADI will be reevaluated when the required toxicity and residue chemistry data are submitted and evaluated.

4. Label Warning Statements:

All Manufacturing-Use Products

Do not discharge effluent containing this product into lakes, streams, ponds, estuaries, oceans, or public water unless this product is specifically identified and addressed in an NPDES permit. Do not discharge effluent containing this product to sewer systems without previously notifying the sewage treatment plant authority. For guidance contact your State Water Board or Regional Office of the EPA.

Technical grade ethephon must be stored and used in ventilated areas only.

End-Use Products

Do not apply directly to water or wetlands (swamps, bogs, marshes, and potholes). Do not contaminate water when disposing of equipment washwaters.

Mixers, loaders and applicators must wear a full face shield, long trousers, long sleeved shirt, gloves, and boots to avoid as much skin and eye contact as possible.

Do not enter treated fields within 24-hours after application.

The following interim pre-harvest intervals (PHI) must be included on end use product labels for the raw agricultural commodities listed. These interim PHI's may be revised after the required field residue data have been submitted and evaluated.

Apples minimum 7 days, barley 40 days, blackberries and blueberries 42 days, cherries minimum 7 days, coffee beans 14 days, cotton 14-21 days, cranberries 17-21 days, cucumbers 17-21 days, figs 14 days, filberts 7 days, grapes 14 days, guavas 7 months, melons 2 days, peppers 14 days, pineapples 2 days, tangerines 5-10 days, tomatoes 14-20 days for processing and 3-6 days fresh market California only, walnuts 5-10 days, wheat 40 days.

6. Summary of Regulatory Positions

1. Ethephon does not meet any of the criteria specified in 40 CFR 154.7; therefore a Special Review is not being initiated at this time.

2. The Agency will not require restricted use classification for ethephon end-use products.

3. The Agency is deferring decisions concerning ethephon's potential for contaminating ground water until information on its environmental characteristics and fate have been submitted and and reviewed.

4. The Agency has identified certain data that will receive immediate review when submitted.

5. The Agency has determined that foliar and soil dislogeable residue data are required to establish reentry intervals for all crops. An interim reentry interval of 24 hours is being imposed for all crops until final reentry reentry intervals are established.

6. Pre-harvest intervals are required on product labeling for a variety of currently registered use sites.

7. The Agency is requiring data on animal metabolism as well as storage stability studies and residue studies for poultry and eggs. In order to remain in compliance with FIFRA, registrants must do one of the following:

a. Submit data which demonstrate that no residues remain in eggs and poultry as a result of feeding treated commodities;

b. Propose tolerances and provide appropriate supporting data for residues in poultry tissues and eggs.

8. Additional residue data, including processing data, must be submitted for the following raw agricultural commodities: peppers, tomatoes, cucumbers, melons, lemons, tangerines, apples, cherries, blackberries, boysenberries, blueberries, cranberries, grapes, filberts, walnuts, barley (wheat data may substitute), wheat, (and wheat straw), coffee beans, cotton seed, figs, guavas, pineapples, sugarcane, and tobacco. For tobacco, pyrolysis data must be submitted. If residues concentrate in any of the processed products, the appropriate food additive tolerance(s) must be proposed. Specific data requirements may be found in the data tables.

9. The Agency is requiring the proposal of either a tolerance for sugarcane forage or a grazing prohbition for sugarcane forage.

10. The Agency has determined that the following revisions in the tolerances listed in 40 CFR 180.300 and 21 CFR 193.186 are necessary.

- o The designation "N" (negligible) must be deleted from all tolerances entries.
- o The commodity "pineapple fodder" must be deleted from 40 CFR 180.300.
- o The tolerance for guava must be added to 40 CFR 180.300.
- o The tolerance for raisins must be added to 21 CFR 193.186.

11. Product chemistry and residue data are required depicting residues of monochloroacetic acid in or on food and feed commidities following registered applications of ethephon. Monochloroacetic acid may be a toxic metabolic residue derived from an impurity in technical ethephon.

12. The Agency has identified 2-chloroethanol as a contaminant of toxicological concern. The Agency is requiring data to assess the extent of contamination with this substance. Additionally, the Agency is requiring that manufacturing use products bear a label statement advising users to store and use the product in well-ventilated areas.

13. While the data gaps are being filled, currently registered manufacturing-use products and end-use products containing ethephon as the sole active ingredient may be sold, distributed, formulated, and used in the United States, subject to the terms and conditions specified in this Standard. Registrants must provide or agree to develop additional data, required in the Registration Standard.

The Agency will issue registrations for substantially similar products and new uses will be issued after considering the effects on the theoretical maximum residue contribution (TMRC) and the maximum permissable intake (MPI).

7. Summary of Major Data Gaps

Data Required	Due Date (After Issuance of the Standard)
Product Chemistry	6 - 12 Months
Hydrolysis	9 Months
Photodegradation	9 Months
Soil Metabolism	27 Months
Fish Accumulation	12 Months
Rotational Crops	39 Months
Leaching and Adsorption/ Desorption	12 Months
Terrestrial Field Dissipation	27 Months
Acute Estuarine and Marine Organisms	12 Months
Acute Inhalation	9 Months
Reproduction	39 Months
Mutagenicity	12 Months
Animal Metabolism	18 Months
Magnitude of Plant Residues	6 - 24 Months
Analytical Methods	15 Months
Storage Stability	18 Months
Chronic Toxicity Rodent	9 Months*
Oncogenicity data	9 Months*

*These studies may be upgraded or they will have to be repeated.

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6. Contact Person at EPA

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